IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

IN RE: DIET DRUGS (PHENTERMINE/ FENFLURAMINE/DEXFENFLURAMINE) PRODUCTS LIABILITY LITIGATION	)	MDL NO. 1203
THIS DOCUMENT RELATES TO:	)	
SHEILA BROWN, et al.	)	
v.	)	CIVIL ACTION NO. 99-20593
AMERICAN HOME PRODUCTS CORPORATION	)	2:16 MD 1203

MEMORANDUM IN SUPPORT OF SEPARATE PRETRIAL ORDER NO. 8213

Bartle, C.J. July 1, 2009

Barbara Laue ("Ms. Laue" or "claimant"), a class member under the Diet Drug Nationwide Class Action Settlement Agreement ("Settlement Agreement") with Wyeth,[1] seeks benefits from the AHP Settlement Trust ("Trust"). Based on the record developed in the show cause process, we must determine whether claimant has demonstrated a reasonable medical basis to support her claim for Matrix Compensation Benefits ("Matrix Benefits").[2]

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1. Prior to March 11, 2002, Wyeth was known as American Home Products Corporation.

2. Matrix Benefits are paid according to two benefit matrices (Matrix "A" and Matrix "B"), which generally classify claimants for compensation purposes based upon the severity of their medical conditions, their ages when they are diagnosed, and the presence of other medical conditions that also may have caused or contributed to a claimant's valvular heart disease ("VHD"). See Settlement Agreement §§ IV.B.2.b. & IV.B.2.d.(1)-(2). Matrix A-1 describes the compensation available to Diet Drug Recipients with

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To seek Matrix Benefits, a claimant must first submit a completed Green Form to the Trust. The Green Form consists of three parts. The claimant or the claimant's representative completes Part I of the Green Form. Part II is to be completed by the claimant's attesting physician, who must answer a series of questions concerning the claimant's medical condition that correlate to the Matrix criteria set forth in the Settlement Agreement. Finally, claimant's attorney must complete Part III if claimant is represented.

In April 2003, claimant submitted a completed Green Form to the Trust signed by her attesting physician, Stephen Raskin, M.D. Based on an echocardiogram dated December 30, 2002, Dr. Raskin attested in Part II of claimant's Green Form that she suffered from moderate mitral regurgitation and an abnormal left atrial dimension.[3] Based on such findings, claimant would be

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serious VHD who took the drugs for 61 days or longer and who did not have any of the alternative causes of VHD that made the B matrices applicable. In contrast, Matrix B-1 outlines the compensation available to Diet Drug Recipients with serious VHD who were registered as having only mild mitral regurgitation by the close of the Screening Period or who took the drugs for 60 days or less or who had factors that would make it difficult for them to prove that their VHD was caused solely by the use of these diet drugs.

3. Dr. Raskin also attested that Ms. Laue had moderate aortic regurgitation. As Ms. Laue's claim does not present any of the complicating factors necessary to receive Matrix Benefits for damage to her aortic valve, her level of aortic regurgitation is not relevant to this claim. See Settlement Agreement §
(continued...)

entitled to Matrix A-1, Level II benefits in the amount of $486,424.[4]

In the report of claimant's echocardiogram, Helbert V. Acosta, M.D., the reviewing cardiologist, stated that claimant had moderate mitral regurgitation, which he measured as 40%. Under the definition set forth in the Settlement Agreement, moderate or greater mitral regurgitation is present where the Regurgitant Jet Area ("RJA") in any apical view, is equal to or greater than 20% of the Left Atrial Area ("LAA"). See Settlement Agreement § I.22. Dr. Acosta also measured claimant's left atrial dimension as 55.3 mm. The Settlement Agreement defines an abnormal left atrial dimension as a left atrial supero-inferior systolic dimension greater than 5.3 cm in the apical four chamber view or a left atrial antero-posterior systolic dimension greater than 4.0 cm in the parasternal long axis view. See id. § IV.B.2.c.(2)(b).

3(...continued)
IV.B.2.c.(2)(a).

4. Under the Settlement Agreement, a claimant is entitled to Level II benefits for damage to the mitral valve if he or she is diagnosed with moderate or severe mitral regurgitation and one of five complicating factors delineated in the Settlement Agreement. See Settlement Agreement § IV.B.2.c.(2)(b). As the Trust did not contest the attesting physician's finding of an abnormal left atrial dimension, which is one of the complicating factors needed to qualify for a Level II claim, the only issue is claimant's level of mitral regurgitation.

In October 2005, the Trust forwarded the claim for review by Siu-Sun Yao, M.D., F.A.C.C., one of its auditing cardiologists. In audit, Dr. Yao concluded that there was no reasonable medical basis for the attesting physician's finding of moderate mitral regurgitation because claimant's echocardiogram demonstrated only mild mitral regurgitation. Dr. Yao concluded that certain technical settings were improper resulting in a "falsely increase[d] appearance of MR." Specifically, Dr. Yao stated that the "Nyquist limit [was] low" and the "[c]olor gain appearance [was] too high."

Based on the auditing cardiologist's diagnosis of mild mitral regurgitation, the Trust issued a post-audit determination denying Ms. Laue's claim. Pursuant to the Rules for the Audit of Matrix Compensation Claims ("Audit Rules"), claimant contested this adverse determination.[5]

In contest, claimant submitted a declaration from Dr. Raskin, who reviewed claimant's echocardiogram for a second time. In the declaration, Dr. Raskin stated that:

> I re-reviewed Barbara Laue's December 30, 2002 echocardiogram with particular attention

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5. Claims placed into audit on or before December 1, 2002 are governed by the Policies and Procedures for Audit and Disposition of Matrix Compensation Claims in Audit, as approved in Pretrial Order ("PTO") No. 2457 (May 31, 2002). Claims placed into audit after December 1, 2002 are governed by the Audit Rules, as approved in PTO No. 2807 (Mar. 26, 2003). There is no dispute that the Audit Rules contained in PTO No. 2807 apply to Ms. Laue's claim.

to Dr. Yao's concerns and I respectfully disagree with Dr. Yao's conclusion that moderate MR, as defined in the Green Form by Singh, *et. al.*, is not present.

My review of the study finds that the December 30, 2002 echocardiogram reveals a central MR jet. Dr. Yao raises concern regarding "inappropriate" Nyquist settings. However, the section of the color-Doppler study performed with lower than recommended Nyquist velocities are explicitly excluded from the analysis of MR severity. Additionally, an appropriate Nyquist setting of 51 cm/s is present in the Laue study and is utilized for the determination of the mitral RJA and MR severity. While appropriate Nyquist settings are important, the Nyquist velocity in this case definitely *exceeds* the minimal Nyquist requirement of 50-60cm/s as defined by the American Society of Echocardiogaphy 2003 recommendations for the evaluation of native valvular regurgitation. Thus, there is no basis for Dr. Yao's claim of any over-representation of the MR severity by manipulation of the Nyquist velocity.

Additionally, Dr. Yao comments about excessive gain settings in the Laue study as another manipulation to enhance MR severity. While Dr. Yao is correct that over-representation of color flow maps may involve excessive color gain manipulation, such manipulation or "dial-a-jet phenomenon" is easy to discern and is not present in this case. Excessive color gain is apparent when background color speckling is evident in the tissues. My careful review of the Barbara Laue study simply does not reveal any increased color or speckling in the tissues, i.e., there are no color pixels in non-moving regions resulting in any "bleeding" of color onto the gray scale of the surrounding tissue. Thus, Dr. Yao's generic concern about "gain" is not applicable to the Laue study.

> Some inter-observer variability is common in the assessment of 2D echo-Doppler studies and any estimate of mitral RJA. My review of the study does find some discrepancy in the estimate of mitral RJA (EXHIBIT B and C) as traced in this study. Nevertheless, the correct estimate of the mitral RJA/LAA ratio is 25% and remains consistent with the AHP Trust definition for moderate MR.

Based on claimant's contest, the Trust submitted the claim to Dr. Yao for a second review. Dr. Yao reaffirmed his initial finding of mild mitral regurgitation. In particular, Dr. Yao stated:

> I again observed that Claimant does have mitral regurgitation, but that the excessive color gain combined with the low Nyquist setting (51 cm/sec) used on the study exaggerated the appearance of Claimant's regurgitant jet area. Based on my review, Claimant's regurgitant jet area to left atrial area ratio never reached 20%.

The Trust then issued a final post-audit determination, again denying Ms. Laue's claim. Claimant disputed this final determination and requested that the claim proceed to the show cause process established in the Settlement Agreement. See Settlement Agreement § VI.E.7; PTO No. 2807, Audit Rule 18(c). The Trust then applied to the court for issuance of an Order to show cause why Ms. Laue's claim should be paid. On March 31, 2006, we issued an Order to show cause and referred the matter to the Special Master for further proceedings. See PTO No. 6111 (Mar. 31, 2006).

Once the matter was referred to the Special Master, the Trust submitted its statement of the case and supporting documentation. Claimant then served a response upon the Special Master. The Trust submitted a reply on June 16, 2006. Under the Audit Rules, it is within the Special Master's discretion to appoint a Technical Advisor[6] to review claims after the Trust and claimant have had the opportunity to develop the Show Cause Record. See Audit Rule 30. The Special Master assigned a Technical Advisor, James F. Burke, M.D., to review the documents submitted by the Trust and claimant and to prepare a report for the court. The Show Cause Record and Technical Advisor's Report are now before the court for final determination. See id. Rule 35.

The issue presented for resolution of this claim is whether claimant has met her burden in proving that there is a reasonable medical basis for the attesting physician's finding of moderate mitral regurgitation. See id. Rule 24. Ultimately, if we determine that there is no reasonable medical basis for the

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6. A "[Technical] [A]dvisor's role is to act as a sounding board for the judge-helping the jurist to educate himself in the jargon and theory disclosed by the testimony and to think through the critical technical problems." Reilly v. U.S., 863 F.2d 149, 158 (1st Cir. 1988). In cases, such as here, where there are conflicting expert opinions, a court may seek the assistance of the Technical Advisor to reconcile such opinions. The use of a Technical Advisor to "reconcil[e] the testimony of at least two outstanding experts who take opposite positions" is proper. Id.

answer in claimant's Green Form that is at issue, we must affirm the Trust's final determination and may grant such other relief as deemed appropriate. See id. Rule 38(a). If, on the other hand, we determine that there is a reasonable medical basis, we must enter an Order directing the Trust to pay the claim in accordance with the Settlement Agreement. See id. Rule 38(b).

In support of her claim, Ms. Laue argues that the findings of Dr. Raskin provide a reasonable medical basis for her claim. Claimant again sets forth Dr. Raskin's declaration addressing the improper settings asserted by Dr. Yao. Claimant discusses Dr. Raskin's disagreement with Dr. Yao regarding the Nyquist settings, noting Dr. Raskin's opinion that the Nyquist velocity actually exceeds the minimal Nyquist requirement of 50-60 cm/s. Claimant also argues that in his second review, Dr. Raskin noted no indication of excessive color gain manipulation in the echocardiogram. Finally, claimant stated that Dr. Raskin reviewed the echocardiogram with sensitivity to the concept of inter-reader variability and still found that claimant had moderate mitral regurgitation.

In response, the Trust argues that claimant's echocardiogram settings were substandard, significantly inflating the measurements made in connection with the study.

The Technical Advisor, Dr. Burke, reviewed claimant's echocardiogram and concluded that there was a reasonable medical

basis for the attesting physician's finding of moderate mitral regurgitation. In particular, Dr. Burke determined that:

> My impression of the December 30, 2002 echocardiogram, by visual inspection, is that the mitral regurgitation is moderate. I would concur with the comments of Stephen Raskin, M.D. that a Nyquist limit of 51 cm/sec is in an acceptable range to adequately assess the severity of mitral regurgitation. I do not note excessive color gain.
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> Using beats from the parasternal long axis view, I measured the RJA/LAA ratio to range from 12% to 35% with an average RJA/LAA ratio of 24%, representing moderate mitral regurgitation.
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> I only found one clip store of the apical four chamber view with color flow Doppler. I measured the RJA/LAA ratio at 33% in this view, representing moderate mitral regurgitation.
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> Using beats in the apical two chamber view, I measured the RJA/LAA ratio to range from 24% to 36% with an average of 29%, representing moderate mitral regurgitation.
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> Using beats in the apical three chamber view, I measured the RJA/LAA ratio to range from 19% to 26% with an average value of 23%, representing moderate mitral regurgitation.
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> In conclusion, I believe there is a reasonable medical basis for the Attesting Physician's answer to Green Form Question C.3.a., which states that Claimant suffers from moderate mitral regurgitation.

Claimant submitted a letter to the Special Master requesting that her claim be paid in light of the Technical

Advisor's favorable report.[7] After reviewing the entire Show Cause Record before us, we find that claimant has established a reasonable medical basis for her claim. Claimant's attesting physician reviewed claimant's echocardiogram twice and found that claimant had moderate mitral regurgitation. Although the Trust challenged the attesting physician's conclusion, Dr. Burke confirmed the attesting physician's finding of moderate mitral regurgitation. Specifically, Dr. Burke concluded that claimant's average RJA/LAA ratios in the various views ranged from 23% to 33%.

As stated above, moderate or greater mitral regurgitation is present where the RJA in any apical view is equal to or greater than 20% of the LAA. See Settlement Agreement § I.22. Here, Dr. Burke measured multiple views and determined that claimant's level of mitral regurgitation was greater than 20%. Under these circumstances, claimant has met her burden in establishing a reasonable medical basis for her claim.

For the foregoing reasons, we conclude that claimant has met her burden in proving that there is a reasonable medical basis for her claim and is consequently entitled to Matrix A-1,

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7. Despite an opportunity to do so, the Trust did not submit a response to the Technical Advisor Report. See Audit Rule 34.

Level II benefits. Therefore, we will reverse the Trust's denial of the claim submitted by Ms. Laue for Matrix Benefits.